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| 08/915,659 | 08/21/97 | O'BRIEN | T D6020 |

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| EXAMINER | |
|-------------|--------------|
| JACOBSON, D | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 08/27/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/915,1659

Applicant(s)

O'Brien

Examiner

Jacobson

Group Art Unit

1652

#9

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-11 is/are pending in the application.
- ☐ Of the above claim(s) 9-10 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8, 11 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-11 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8 and 11, drawn to DNA encoding a TADG-14 protein, vectors, host cells, and a method of detection, classified in class 435, subclass 6.
- II. Claims 9-10, drawn to a TADG-14 protein, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The DNA sequences of Group I and the proteins of Group II are independent chemical entities and require different literature searches. The host cell and method of detection claims are placed with the DNA sequences of Group I because although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search in addition to the DNA sequence.

During a telephone conversation with Dr. Benjamin Adler on July 20, 1998, a provisional election was made without traverse to prosecute the invention of group I, claims 1-8 and 11.

Affirmation of this election must be made by applicant in responding to this Office action. Claims 9-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicants' submission of a sequence listing is noted.

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Applicants' abstract is noted. The abstract recites "TADG-14", but does not recite the full name of the protein. In order to avoid confusion and to completely convey the subject matter of the invention it is suggested that applicants amend the abstract to recite the full name of the protein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6-8, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the claimed invention.

Claim 1 is drawn to a DNA encoding a "TADG-14" protein. The specification teaches that this protein was isolated from ovarian cancer cells and identified in other carcinoma cells. The specification discloses the amino acid and nucleic acid sequences of a specific TADG-14 molecule. The function(s) of this protein is not disclosed. The specification does not provide other identifying characteristics of this protein such that one of skill in the art would know if a TADG-14 protein had been obtained. It is unknown if there are other members of a TADG family. A description of a particular species is not a sufficient description of a broad class of proteins. The specification does not provide enough information such that one skilled in the art

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would be able to readily envision a sufficient number of members of the claimed genus, i.e., a TADG-14 protein, to provide adequate written description support for the genus.

This rejection may be overcome by limiting the claims to the disclosed sequences.

Claims 1, 4, 6-8, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed nucleic acid molecules encoding TADG-14, does not reasonably provide enablement for all the nucleic acid molecules encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 is drawn to a DNA which hybridizes to a DNA encoding TADG-14. The claim does not limit the hybridization conditions and includes any conditions. Applicants have disclosed a specific sequence encoding TADG-14 (SEQ ID NO. 6 and 7). Applicants have not disclosed other proteins and/or nucleic acid sequences. The disclosed DNA sequence was not known in the art at the time the invention was made. Thus there is a high level of unpredictability. Due to the many possible DNA molecules, the lack of guidance presented either by applicants or in the art regarding other TADG-14 molecules, and the unpredictable nature of the invention, it would require undue experimentation for one of skill in the art to isolate and identify all of the possible DNA molecules encoding TADG-14 encompassed by the claims. The claims are deemed to be beyond the scope of the enabling disclosure.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in its recitation of "TADG-14" because the identity of the protein is not clear. Amending the claims to recite that protein's complete name may overcome this rejection.

Claim 11 recites a method to detect expression of the *protein* of claim 1. Claim 1 is drawn to a *DNA molecule*. Part (a) lacks antecedent basis for "the cell" and "the probe".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (J. Neurosci. 15:5088-5097).

Chen et al. describe isolation and characterization of neuropsin, a serine protease. The reference teaches the nucleic acid and amino acid sequences of this enzyme. The reference also describes cloning of the enzyme.

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The nucleic acid sequence encoding neuropsin is 77% homologous to applicants' SEQ ID NO. 6. Claim 1 is drawn to a DNA that hybridizes under any condition and which encodes a TADG-14 protein. Absent evidence to the contrary, the neuropsin gene described by Chen et al. would be expected to hybridize to applicants' SEQ ID NO. 6. The claims are thus anticipated by the reference.

Claims 2, 3, and 5 are free of prior art.


Tanimoto et al. (Cancer Research 57:2884-2887) is cited of interest but is not relevant prior art.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1652**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dian C. Jacobson whose telephone number is (703) 308-2973. The examiner can normally be reached Monday, Tuesday, and Thursday from 7:30 to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The official FAX number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


DIAN C. JACOBSON
PRIMARY EXAMINER
GROUP 1652 1652